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IN THE UNITED STATES DISTRICT COURT  
 FOR THE DISTRICT OF NEW JERSEY

GLAXOSMITHKLINE PLC;  
 GLAXOSMITHKLINE LLC; GLAXO  
 GROUP LIMITED, SMITHKLINE  
 BEECHAM LIMITED ; PFIZER, INC.;  
 ENCYSIVE PHARMACEUTICALS, INC.;

*Plaintiffs – Counterclaim Defendants,*

MITSUBISHI CHEMICAL CORP.; and  
 MITSUBISHI TANABE PHARMA CORP.,

*Involuntary Plaintiffs – Counterclaim  
 Defendants,*

v.

HIKMA PHARMACEUTICAL CO., LTD.;  
 and WEST-WARD PHARMACEUTICAL  
 CORP.,

*Defendants – Counterclaim Plaintiffs.*

C.A. No. 3:12-CV-01965-FLW-DEA

JURY TRIAL DEMANDED

Document Electronically Filed

**DEFENDANTS' ANSWER TO FIRST AMENDED COMPLAINT,  
SEPARATE DEFENSES, AND COUNTERCLAIMS**

Defendants Hikma Pharmaceutical Co., Ltd. ("Hikma") and West-Ward

Pharmaceutical Corp. (“West-Ward”) (collectively “Defendants”), by and through their undersigned counsel, answer and respond to each of the allegations in Plaintiffs GlaxoSmithKline plc, GlaxoSmithKline LLC, Glaxo Group Limited, and SmithKline Beecham Limited (collectively “GSK”), Pfizer, Inc., (“Pfizer”), Encysive Pharmaceuticals, Inc. (“Encysive”), Mitsubishi Chemical Corp. (“MCC”) and Mitsubishi Tanabe Pharma Corp.’s (“MTPC”) (collectively, “Plaintiffs”) First Amended Complaint, as follows:

**ANSWER**

1. GSK plc (“GSK plc”) is a British company, having its registered office at 980 Great West Road, Brentford, Middlesex, TW8 9GS, England. GSK is a worldwide, research-based pharmaceutical and healthcare company, producing and marketing a variety of medicines, vaccines, and consumer products.

**Answer**

Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and deny the allegations on that basis.

2. GlaxoSmithKline LLC (“GSK LLC”) (formerly known as SmithKlineBeecham Corporation) is a Delaware limited liability company having a principal place of business at One Franklin Plaza, 200 North 16th Street, Philadelphia, PA 19102. GSK LLC is an indirect, wholly-owned subsidiary of GSK plc.

**Answer**

Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and deny the allegations on that basis.

3. Glaxo Group Limited (“GGL”) is a company organized and existing under the laws of England and Wales having its registered office in Greenford, England. GGL is an indirect, wholly-owned subsidiary of GSK plc.

**Answer**

Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and deny the allegations on that basis.

4. SmithKline Beecham Limited (“SKB Ltd.”) (formerly known as SmithKline Beecham plc) is a company organized and existing under the laws of England having its registered office in Brentford, England. SKB Ltd. is an indirect, wholly-owned subsidiary of GSK plc.

**Answer**

Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and deny the allegations on that basis.

5. Pfizer is a Delaware corporation, having its principal place of business at 235 East 42nd Street, New York, NY 10017. Pfizer is a pharmaceutical and biotechnology company applying science and global resources to improve health and well-being, focusing on quality, safety, and value in the discovery, development, and manufacturing of medicines for people and animals.

**Answer**

Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and deny the allegations on that basis.

6. Encysive is a Delaware corporation having its corporate headquarters and principal place of business in Houston, Texas. Encysive is a biopharmaceutical company engaged in the discovery, development, and commercialization of novel compounds to address unmet medical needs. Pfizer acquired Encysive in 2008.

**Answer**

Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and deny the allegations on that basis.

7. MCC, joined as an involuntary plaintiff, is a Japanese corporation, having its headquarters and principal place of business in Tokyo, Japan. MCC is engaged in the business of employing the science of chemistry to create, develop, and improve products with a particular focus on the areas of petrochemicals, performance and functional products, and healthcare.

**Answer**

Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and deny the allegations on that basis.

8. MTPC, joined as an involuntary plaintiff, is a Japanese corporation having its headquarters and principal place of business in Osaka, Japan. MTPC is a pharmaceutical company that engages in the development, manufacture, and marketing of a broad spectrum of innovative pharmaceutical products.

**Answer**

Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and deny the allegations on that basis.

9. Upon information and belief, Hikma is a Jordanian company, having its registered address at Bayader Wadi El-Seer, Industrial Area, P.O. Box 182400, Amman, Jordan, 11118. Hikma is a worldwide pharmaceutical company in the business of developing and manufacturing injectables and branded and generic drugs. Hikma is the wholly-owned subsidiary of Hikma Pharmaceutical PLC, a U.K. holding company.

**Answer**

Admitted.

10. Upon information and belief, West-Ward is a Delaware corporation, having its principal place of business at 401 Industrial Way West, Eatontown, NJ 07724-2206. West-Ward is in the business of generic pharmaceutical manufacturing and distribution. West-Ward is an agent and wholly-owned subsidiary of Hikma Pharmaceutical PLC.

**Answer**

Admitted.

**JURISDICTION AND VENUE**

11. This is an action for patent infringement arising under the patent laws of the United States, specifically 35 U.S.C. §§ 271(e)(2), 271(b), 271(c), and 281-283.

**Answer**

Defendants admit that the claims alleged in the Complaint arise under the patent laws of the United States and that Plaintiffs purport to bring an action for patent

infringement.

12. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

**Answer**

Defendants admit that this Court has subject matter jurisdiction over this action.

13. Venue is proper under 28 U.S.C. §§ 1391(b)-(d) and 1400(b).

**Answer**

For purposes of this action only, Defendants do not contest that venue is proper.

14. Defendant West-Ward is properly subject to personal jurisdiction in the State of New Jersey (the “State”) because West-Ward has its headquarters and principal place of business within the State.

**Answer**

West-Ward admits that its headquarters and principal place of business are located in the State of New Jersey and that it is subject to personal jurisdiction in the State of New Jersey.

15. Upon information and belief, West-Ward and Hikma are agents of each other and/or operate in concert as integrated parts of Hikma’s generic business.

**Answer**

Denied.

16. Upon information and belief, Hikma has knowingly placed its products in New Jersey’s stream of commerce by acting in concert with West-Ward to market and sell generic drug products throughout the United States, including in New Jersey.

**Answer**

Denied.

17. Upon information and belief, and according to Hikma’s website, <http://www.hikma.com>, West-Ward was acquired by Hikma in 1991 in order to establish its presence in the United States. This was prior to the formation of the Hikma Pharmaceutical PLC holding company, which is now the parent of both wholly-owned subsidiaries Hikma and West-Ward.

**Answer**

Defendants admit that Hikma acquired West-Ward in 1991 and that Hikma and West-Ward are indirect wholly-owned subsidiaries of Hikma Pharmaceutical PLC. Defendants also admit that Hikma Pharmaceutical PLC was not formed as of 1991. Defendants deny the remaining allegations of this paragraph.

18. Upon information and belief, and according to West-Ward's website, <http://www.west-ward.com>, West-Ward is "one of the top 20 generic prescription medication providers in the US, providing pharmaceuticals to a growing number of chain stores, wholesalers, distributors, health systems and government agencies. We are the US agent and subsidiary of Hikma PLC."

**Answer**

Defendants' admit that Plaintiffs have accurately quoted from West-Ward's website. Defendants deny the remaining allegations of this paragraph.

19. Upon information and belief, and according to Hikma's website, Hikma's generics business is focused entirely on the United States market, and operates as West-Ward, which manufactures and/or markets over 50 generic compounds in the United States and New Jersey.

**Answer**

Defendants admit that Hikma's website states "Our Generics business is entirely focused on the US market for oral generics" and that West-Ward Pharmaceuticals is "a domestic marketer and manufacturer of generic pharmaceutical products, selling 50 generic compounds in 122 dosage forms and strengths." Defendants deny the remaining allegations of this paragraph.

20. Upon information and belief, Hikma has filed New Drug Applications ("NDAs") or Abbreviated New Drug Applications ("ANDAs") with the Food and Drug Administration ("FDA"), requesting permission to market, throughout the United States (including in New Jersey), a number of generic drugs, including a generic copy of GSK's Argatroban Injection (the "Proposed Hikma Product").

**Answer**

Defendants admit that Hikma filed Section 505(b)(2) NDA No. 203049 with the FDA requesting permission to market an argatroban injection product in the United States and that Hikma has filed NDAs and ANDAs with the Food and Drug Administration for other pharmaceutical products. Defendants further admit that New Jersey is in the United States. Defendants deny the remaining allegations of this paragraph.

21. Upon information and belief, West-Ward is the distributor of drugs for which Hikma is the named applicant on the FDA's Approved Drug Product List. Upon information and belief, West-Ward, acting as the agent of Hikma, markets Hikma's drug products in New Jersey and elsewhere in the United States.

**Answer**

Defendants admit that West-Ward has distributed drugs in the United States for which Hikma is the applicant named on the FDA's Approved Drug Product List. Defendants deny the remaining allegations of this paragraph.

22. Upon information and belief, Hikma intends to engage in the commercial manufacture, use, offering for sale, and sale of the Proposed Hikma Product imminently, actions that will directly or indirectly infringe GSK's intellectual property rights within the State of New Jersey.

**Answer**

Defendants admit that Hikma intends to engage in the commercial manufacture, use, offer for sale and sale of the Proposed Hikma Product. Defendants deny the remaining allegations of this paragraph.

23. Upon information and belief, West-Ward is the intended U.S. distributor for the Proposed Hikma Product, and is thereby acting in concert with Hikma to market and/or sell the infringing generic product within the boundaries of New Jersey, and thus to commit tortious acts therein.

**Answer**

Defendants admit that West-Ward may distribute the Proposed Hikma Product in

the United States. Defendants deny the remaining allegations of this paragraph.

24. Upon information and belief, Hikma earns revenue from West-Ward's marketing and distribution in New Jersey of generic pharmaceutical products that are manufactured by Hikma or for which Hikma is the named applicant on approved NDAs or ANDAs.

**Answer**

Denied.

25. Upon information and belief, upon launch, the Proposed Hikma Product charged with infringing the patent-in-suit, will, among other things, be marketed and distributed by West-Ward, acting as the U.S. agent of Hikma, in New Jersey, prescribed by physicians practicing in New Jersey, and dispensed by hospital pharmacies located within New Jersey, all of which would have a substantial effect on the State.

**Answer**

Defendants admit that West-Ward may distribute the Proposed Hikma Product in the United States. Defendants deny the remaining allegations of this paragraph.

26. Hikma is subject to personal jurisdiction in the State of New Jersey, under N.J. Ct. R. 4:4-4(b)(1), because, *inter alia*, it has maintained systematic and continuous contacts with the State, including through its relationship with West-Ward.

**Answer**

Denied, but for purposes of this action only, Hikma will not dispute that this Court has personal jurisdiction over it.

27. Hikma also is subject to personal jurisdiction in the State of New Jersey because it has purposefully availed itself of the legal protections of the State by admitting jurisdiction and asserting counterclaims in a lawsuit filed in 2003, *Glaxo Group Ltd. v. West-Ward Pharmaceuticals, Inc.*, No. 03-CV-4791(JLL)(D.N.J. 2003), seeking a declaratory judgment that the asserted patents in that case were invalid, unenforceable, and not infringed.

**Answer**

Denied, but for purposes of this action only, Hikma will not dispute that this Court has personal jurisdiction over it.

### **GENERAL ALLEGATIONS**

28. This case involves United States Patent No. 5,214,052 (the “‘052 Patent”), entitled “Method for Dissolving Arginineamides and Pharmaceutical Compositions Containing Them,” a true and correct copy of which is attached hereto as Exhibit A. The ‘052 Patent was duly issued on May 25, 1993 to inventors Kunihiro Ofuchi and Tatsuo Nomura, and assigned to MCC (then known as Mitsubishi Kasei Corporation).

#### **Answer**

Defendants admit that Plaintiffs have alleged infringement of the ‘052 patent in their Complaint, that the ‘052 patent is entitled “Method for Dissolving Arginineamides and Pharmaceutical Compositions Containing Them,” that the Complaint purports to attach a true and correct copy of the ‘052 patent, and that the face of the ‘052 patent indicates an issue date of May 25, 1993, lists Kunihiro Ofuchi and Tatsuo Nomura as the inventors, and lists Mitsubishi Kasei Corporation as the assignee. Defendants deny the remaining allegations of this paragraph.

29. The ‘052 Patent claims, *inter alia*, a novel injectable pharmaceutical composition comprising 1-[5-[(aminoiminomethyl)amino]-1-oxo-2-[(1,2,3,4-tetrahydro-3-methyl-8-quinoliny) sulfonyl]amino]pentyl]-4-methyl-2-piperidinecarboxylic acid, monohydrate (“argatroban”), dissolved in a solvent containing ethanol, water, and a saccharide, as well as a method of preparing such a composition.

#### **Answer**

Paragraph 26 calls for a legal conclusion to which no response is required. To the extent there are any factual allegations, Defendants deny them.

30. The claims of the ‘052 Patent are valid and enforceable. The United States District Court for the Southern District of New York held that the ‘052 Patent was not invalid and enjoined another generic company from launching a generic version of GSK’s Argatroban Injection. *See Mitsubishi Chem. Corp. v. Barr Labs., Inc.*, 718 F. Supp. 2d 382 (S.D.N.Y. 2010), *aff’d*, 435 F. App’x 927 (Fed. Cir. 2011).

#### **Answer**

Defendants admit that The United States District Court for the Southern District

of New York held that the claims of the '052 Patent were not invalid and enjoined another generic company from launching a generic version of GSK's Argatroban Injection. *See Mitsubishi Chem. Corp. v. Barr Labs., Inc.*, 718 F. Supp. 2d 382 (S.D.N.Y. 2010), *aff'd*, 435 F. App'x 927 (Fed. Cir. 2011). Defendants deny the remaining allegations of this paragraph.

31. MCC has been and is the owner and assignee of the '052 Patent, which is set to expire on June 30, 2014, having received a patent term extension pursuant to 35 U.S.C. § 156.

**Answer**

Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and deny the allegations on that basis.

32. Upon information and belief, MTPC is the successor-in-interest to certain rights in MCC's pharmaceutical business, including rights relating to Argatroban Injection. MTPC holds an exclusive license to the '052 Patent, with the right to sublicense, as well as certain rights through a license agreement between MCC and Encysive relating to Argatroban Injection.

**Answer**

Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and deny the allegations on that basis.

33. In 1997, MCC granted Encysive (then Texas Biotechnology Company) an exclusive license to the '052 Patent for the United States. Encysive's exclusive license included the right to further sublicense to GSK's predecessor. Encysive also was the holder of the approved NDA for Argatroban Injection, No. 020833, which was approved on June 30, 2000 by the FDA. By way of acquisition of Encysive, Pfizer now holds an exclusive license to the '052 Patent in the United States and also holds NDA No. 020833 for Argatroban Injection.

**Answer**

Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and deny the allegations on that basis.

34. GSK is the exclusive sublicensee of Pfizer and is the exclusive distributor of Argatroban Injection under NDA No. 020833 in the United States.

**Answer**

Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and deny the allegations on that basis.

35. Under NDA No. 020833, GSK's Argatroban Injection is approved for use as an anticoagulant for prophylaxis or treatment of thrombosis in patients with heparin-induced thrombocytopenia ("HIT"), and also as an anticoagulant in adult patients with or at risk for HIT and undergoing percutaneous coronary intervention ("PCI").

**Answer**

Defendants admit that argatroban injection has approved indications for prophylaxis or treatment of thrombosis in adult patients with heparin-induced thrombocytopenia (HIT) and as an anticoagulant in adult patients with or at risk for HIT undergoing percutaneous coronary intervention (PCI). Defendants deny the remaining allegations of this paragraph.

36. HIT can arise in some patients who receive heparin (an anticoagulant) to prevent clot formation following, among other things, thrombotic events such as heart attacks, occlusions, or strokes; serious trauma resulting in extended periods of bed-rest; or any extracorporeal bypass such as dialysis. Within two weeks of receiving heparin, a sensitized patient may experience an immune response that seriously damages platelets and releases clotting factors into the bloodstream. If the fragmented platelets and clotting factors spread significantly throughout the body, a more serious condition, known as heparin-induced thrombocytopenia and thrombosis ("HITT"), can result.

**Answer**

Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and deny the allegations on that basis.

37. Both HIT and HITT can result in clot formation throughout the body, and if undiagnosed or untreated, can lead to amputation or death. The diagnosis of HIT and HITT can be very difficult because both conditions present with thrombocytopenia (low platelet count), a symptom that can result from a number of other disorders. Furthermore, HIT and HITT are generally asymptomatic until a morbidity or mortality event occurs.

**Answer**

Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and deny the allegations on that basis.

38. GSK's Argatroban Injection is the preferred treatment among healthcare providers for HIT and HITT because, among other reasons, it is excreted by the liver and not the kidneys. Other drugs are excreted through the kidneys, making them less suitable as a treatment for those patients undergoing kidney dialysis. Furthermore, GSK's Argatroban Injection is sold in high concentration and can be diluted for intravenous delivery in lower amounts of fluids, making it more suitable for patients on liquid volume restrictions.

**Answer**

Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and deny the allegations on that basis.

39. Upon information and belief, Defendant Hikma submitted an NDA to the FDA under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the "Act") along with a certification under Section 505(b)(2)(A)(IV) ("Paragraph IV"), requesting approval to market the Proposed Hikma Product in the United States. The FDA assigned NDA No. 203049 to the application.

**Answer**

Admitted.

40. Upon information and belief, Defendant Hikma sent a letter, dated June 3, 2011, providing Paragraph IV Notice of NDA No. 203049 to MCC, Encysive, and Pfizer (the "Paragraph IV Notice").

**Answer**

Admitted.

41. Upon information and belief, Defendant Hikma received notification on January 5, 2012 of the FDA's approval of NDA No. 203049 (the "Approval"), allowing the Proposed Hikma Product to be used for prophylaxis or treatment of thrombosis in adult patients with HIT and as an anticoagulant in adult patients with or at risk for HIT undergoing PCI. The FDA also published Hikma's label for the Proposed Hikma Product.

**Answer**

Admitted.

42. Upon information and belief, the Proposed Hikma Product has been given an “AP” rating by the FDA, which means that the FDA has deemed it bioequivalent to GSK’s Argatroban Injection.

**Answer**

Defendants admit that the Proposed Hikma Product has been given an “AP” rating by the FDA, which means that the FDA has deemed it therapeutically equivalent to the reference listed drug. Defendants deny the remaining allegations of this paragraph.

43. Upon information and belief, Hikma intends to engage in the commercial manufacture, use, importation, offering for sale, and sale of the Proposed Hikma Product imminently.

**Answer**

Defendants admit that Hikma intends to engage in the commercial manufacture, use, offering for sale and sale of the Proposed Hikma Product. Defendants deny the remaining allegations of this paragraph.

44. As the owner and licensor of the ‘052 Patent, Mitsubishi is an indispensable party to this action. Upon information and belief, Mitsubishi has an obligation under certain licensing agreements to cooperate with and join in infringement actions brought by Encysive/Pfizer and GSK as its exclusive licensee and exclusive sublicense, respectively, to enforce and protect the ‘052 Patent and GSK’s Argatroban Injection. GSK and Encysive/Pfizer have requested that Mitsubishi voluntarily cooperate with Plaintiffs in this action and join as a plaintiff. To date, Mitsubishi has refused to authorize GSK or Encysive/Pfizer to name MCC and MTPC as plaintiffs in this action.

**Answer**

Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and deny the allegations on that basis.

**COUNT I – INFRINGEMENT OF U.S. PATENT NO. 5,214,052**

45. Plaintiffs repeat and incorporate by reference herein the allegations contained in Paragraphs 1-41 above.

**Answer**

Defendants repeat and incorporate their answers to Paragraphs 1-41 above.

46. Upon information and belief, Defendant Hikma filed and received FDA approval for NDA No. 203049 to manufacture and market the Proposed Hikma Product.

**Answer**

Admitted.

47. Hikma's submission of NDA No. 203049 to obtain approval to market the Proposed Hikma Product prior to the expiration of the '052 Patent constitutes infringement of one or more of the claims of the '052 patent under 35 U.S.C. § 271(e)(2)(A).

**Answer**

Denied.

48. Upon launch of the Proposed Hikma Product, Defendants will further infringe the '052 Patent through the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Hikma Product in or into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c).

**Answer**

Denied.

49. Upon information and belief, Defendants had actual and constructive knowledge of the '052 Patent prior to filing NDA No. 203049 and were aware that filing of the aforementioned NDA with the FDA constituted an act of infringement of the '052 Patent.

**Answer**

Defendants admit they were aware of the '052 patent at the time of the filing NDA No. 203049. Defendants deny the remaining allegations of this paragraph.

50. Unless Defendants are enjoined from infringing the '052 Patent, Plaintiffs will suffer substantial and irreparable injury, for which there is no adequate remedy at law.

**Answer**

Denied.

**PRAYER FOR RELIEF**

WHEREFORE, Defendants deny that Plaintiffs are entitled to any of the relief sought.

**SEPARATE DEFENSES TO PLAINTIFFS' FIRST AMENDED COMPLAINT**

Without altering the burdens of proof, Defendants assert the following separate defenses.

**FIRST SEPARATE DEFENSE**

Defendants will not directly, indirectly, contributorily, and/or by inducement infringe either literally or under the doctrine of equivalents any valid claim of the '052 patent under 35 U.S.C. § 271.

**SECOND SEPARATE DEFENSE**

The claims of the '052 patent are invalid for failure to comply with 35 U.S.C. § 112.

**THIRD SEPARATE DEFENSE**

Upon information and belief, Plaintiffs knew or should have known that Hikma's Proposed Product does not infringe any valid claim of the '052 patent, and nevertheless brought the present action against Defendants for the purpose of wrongfully excluding Defendants from the market. By initiating and maintaining the present action, Plaintiffs have engaged in patent misuse and vexatious litigation, which should bar Plaintiffs from any relief herein.

#### **FOURTH SEPARATE DEFENSE**

Upon information and belief, the claims for relief are precluded by prosecution history estoppel and/or prosecution disclaimer.

#### **FIFTH SEPARATE DEFENSE**

Any additional defenses that discovery may reveal.

#### **COUNTERCLAIMS**

Defendants, for their Counterclaims against Plaintiffs, alleges as follows:

1. Defendant and Counterclaim Plaintiff Hikma is a Jordanian company, having its registered address at Bayader Wadi El-Seer, Industrial Area, P.O. Box 182400, Amman, Jordan, 11118.

2. Defendant and Counterclaim Plaintiff West-Ward is a Delaware corporation, having its principal place of business at 401 Industrial Way West, Eatontown, NJ 07724-2206.

3. On information and belief, Plaintiff and Counterclaim Defendant GSK plc is a British company, having its registered office at 980 Great West Road, Brentford, Middlesex, TW8 9GS, England.

4. On information and belief, Plaintiff and Counterclaim Defendant GlaxoSmithKline LLC is a Delaware limited liability company having a principal place of business at One Franklin Plaza, 200 North 16th Street, Philadelphia, PA 19102.

5. On information and belief, Glaxo Group Limited is a company organized and existing under the laws of England and Wales having its registered office in Greenford, England.

6. On information and belief, SmithKline Beecham Limited is a company organized and existing under the laws of England having its registered office in Brentford, England.

7. On information and belief, Plaintiffs and Counterclaim Defendant Pfizer is a Delaware corporation, having its principal place of business at 235 East 42nd Street, New York, NY 10017.

8. On information and belief, Plaintiffs and Counterclaim Defendant Encysive is a Delaware corporation having its corporate headquarters and principal place of business in Houston, Texas.

9. On information and belief, Involuntary Plaintiff and Counterclaim Defendant MCC is a Japanese corporation, having its headquarters and principal place of business in Tokyo, Japan.

10. On information and belief, Involuntary Plaintiff and Counterclaim Defendant MTPC is a Japanese corporation having its headquarters and principal place of business in Osaka, Japan.

11. This is a declaratory judgment action under the patent laws of the United States, 35 U.S.C. § 1, *et seq.* Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and 1400(b).

13. This Court may declare the rights and legal relation for the parties pursuant to 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271(e)(5).

14. The Plaintiffs have commenced the present action for patent infringement against Defendants in this Court. A definite and concrete, real and substantial, justiciable controversy exists between the parties concerning Defendants' non-infringement and the invalidity of the '052 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

15. Upon information and belief, MTPC has taken steps to establish a base for research and development of pharmaceuticals in the United States, has taken steps to establish a system for sales of MTPC products in the United States, and is committed to creating a strong United States organization.

16. Upon information and belief, MTPC conducts its United States operations, including development, sales, and marketing of pharmaceuticals, through six United States subsidiaries, five of which are wholly owned and three of which are located in New Jersey.

17. Upon information and belief, and according to MTPC's 2011 annual report, Mitsubishi Tanabe Pharma Holdings, America, Inc., is a wholly owned, consolidated subsidiary of MTPC located at 25 Independence Blvd., Suite 202, Warren, New Jersey 07059, that is in the business of managing MTPC's U.S. subsidiaries. Mitsubishi Tanabe Pharma Holdings, America, Inc. is wholly controlled and dominated by MTPC with respect to the general conduct of its business.

18. Upon information and belief, and according to MTPC's 2011 annual report, Mitsubishi Tanabe Pharma Development America, Inc. is a wholly owned, consolidated subsidiary of MTPC located at 25 Independence Blvd., Suite 201, Warren, New Jersey 07059, that is in the business of research and development of

pharmaceuticals. Mitsubishi Tanabe Pharma Development America, Inc. is wholly controlled and dominated by MTPC with respect to the general conduct of its business.

19. Upon information and belief, Mitsubishi Tanabe Pharma Development America, Inc. performs research and development activities on behalf of MTPC.

20. Upon information and belief, and according to Mitsubishi Tanabe Pharma America, Inc.'s ("MTPA") website, the products in Mitsubishi Tanabe Pharma Development America, Inc.'s development portfolio are also identified by MTPC as products in its pipeline.

21. Upon information and belief, and according to MTPC's and MTPA's websites, both MTPC and MTPA consider the same products as having been developed "In-house."

22. Upon information and belief, MTPA is a wholly owned, consolidated subsidiary of MTPC located at 25 Independence Boulevard, Suite 202, Warren, NJ 07059, that is in the business of pharmaceutical sales and marketing. MTPA is wholly controlled and dominated by MTPC with respect to the general conduct of its business.

23. Upon information and belief, MTPC markets products in the United States through its alter ego and agent MTPA.

24. Upon information and belief, and according to a MTPC press release dated 2009, MTPC is developing at least two products for the U.S. market and "[u]pon obtaining approval, Mitsubishi Tanabe Pharma America will launch these products and start marketing and promotion activity in the U.S. market."

25. Upon information and belief, the website of MTPA references, in "The Research" section, products in development at MTPC, uses the names "Mitsubishi

Tanabe Pharma” to refer both MTPC and MTPA, and uses as MTPA’s mark MPTC’s brand mark.

26. Upon information and belief, and according to MTPC’s website and annual report 2011, Tanabe USA, Inc., and Tanabe Research Laboratories USA, Inc., are wholly owned, consolidated subsidiaries of MTPC located in California, and MP Healthcare Venture Management, Inc. is a consolidated subsidiary of MTPC located in Massachusetts.

27. Upon information and belief, and according to MTPC’s website and ClinicalTrials.gov, MTPC has sponsored at least seven clinical trials in the United States, at least three of which have clinical testing sites in New Jersey.

28. Upon information and belief, and according to MTPC’s annual report 2011, MTPC has licensed its products to companies in the United States, including Johnson & Johnson, which is located in New Brunswick, New Jersey.

29. Upon information and belief, MTPC has developed a complete infrastructure in terms of marketing, sales, administration, and distribution of pharmaceuticals in the United States, and this infrastructure includes its subsidiaries in New Jersey.

30. Upon information and belief, MTPC, acting through its subsidiaries, has knowingly placed goods into the stream of commerce for distribution throughout the United States, including New Jersey.

31. Upon information and belief, and according to MTPA’s website, MTPC conducts ongoing, systematic and continuous business activity in New Jersey, including conducting business with its New Jersey subsidiaries, such as by “deliver[ing] innovative

products from Mitsubishi Tanabe Pharma Group's in-house development and strategic external investments" to MTPA and forming "close ties . . . with the U.S. kidney community."

32. Upon information and belief, MTPC controls its New Jersey subsidiaries such that the subsidiaries are mere instrumentalities of MTPC.

33. Upon information and belief, MTPC has the right to control all or nearly all aspects of the operations of its New Jersey subsidiaries.

34. Upon information and belief, the activities of MTPC's New Jersey subsidiaries are sufficiently important that if these subsidiaries did not exist, MTPC would have to perform substantially similar services on its own or through another agent.

35. MTPC's New Jersey subsidiaries are agents and/or alter egos of MTPC.

36. Personal jurisdiction in New Jersey over MTPC's New Jersey subsidiaries is proper because they are located in New Jersey and have purposefully availed itself of the privilege of doing business in this State. Further, the New Jersey subsidiaries maintain continuous and systematic contacts with the State of New Jersey so as to reasonably allow jurisdiction to be exercised over them.

37. Personal jurisdiction in New Jersey over MTPC is proper under N.J. Ct. R. 4:4-4(a) and (b)(1) because it purposefully avails itself of the privilege of developing, marketing, and selling pharmaceuticals and doing business in New Jersey to and through its agents and/ or alter egos – its New Jersey subsidiaries; it has systematic and continuous contacts with New Jersey through these agents and/or alter egos and by doing business with these subsidiaries; and it and can reasonably expect to be subject to jurisdiction in the courts of New Jersey.

38. Alternatively, personal jurisdiction in New Jersey over MTPC is proper under Federal Rule of Civil Procedure 4(k)(2) even if MTPC is not subject to the jurisdiction of New Jersey, because the claims asserted by Hikma and West-Ward arise under Federal law, MTPC is not subject to the jurisdiction of any other state court, and exercising jurisdiction over MTPC is consistent with U.S. law.

39. Upon information and belief, MCC has knowingly placed its products in New Jersey's stream of commerce by shipping products to the United States, including New Jersey, and selling products in the United States, including in New Jersey, alone and through its wholly-owned subsidiary and agent Mitsubishi Chemical USA, Inc.

40. Upon information and belief, MCC, on its own and by and through its subsidiaries develops and distributes performance products, such as electronics, health care products, and industrial materials throughout the world, including the United States.

41. Upon information and belief, MCC conveyed certain rights in the '052 patent to MTPC.

42. Upon information and belief, MCC regularly, continuously, and systematically conducts business with MTPC, and this business includes engaging in asset transfer and licensing agreements.

43. Upon information and belief, and according to MCC's website, MCC has at least seven subsidiaries located in the United States that are wholly controlled and dominated by MCC with respect to the general conduct of the subsidiaries businesses. MCC has subsidiaries located in at least Virginia, South Carolina California, Indiana, Tennessee, and New Jersey.

44. Upon information and belief, and according to MCC's website, USR Optonix Inc., which is also known as MC Optonix LLC, ("Optonix") is a wholly owned, consolidated subsidiary of MCC located at P.O. Box 151, 253 E. Washington Ave., Washington, NJ 07882, that is in the business of phosphors and intensifying screens for radiography.

45. Upon information and belief, Optonix is wholly controlled and dominated by MCC with respect to the general conduct of its business.

46. Upon information and belief, MCC conducts ongoing, systematic and continuous business activity in New Jersey, including conducting business with its New Jersey subsidiary Optonix; conducting business with MTPC; and knowingly placing goods in the stream of commerce for distribution throughout the United States, including New Jersey.

47. Upon information and belief, MCC controls its New Jersey subsidiary Optonix such that it is a mere instrumentality of MCC.

48. Upon information and belief, MCC has the right to control all or nearly all aspects of the operations of its subsidiaries, including Optonix.

49. Upon information and belief, the activities of MCC's subsidiaries, including Optonix, are sufficiently important that if these subsidiaries did not exist, MCC would have to perform substantially similar services on its own or through another agent.

50. MCC's subsidiaries are agents and/or alter egos of MCC.

51. Personal jurisdiction in New Jersey over Optonix is proper because it is located in New Jersey and has purposefully availed itself of the privilege of doing

business in this State. Further, Optonix maintains continuous and systematic contacts with the State of New Jersey so as to reasonably allow jurisdiction to be exercised over it.

52. Personal jurisdiction in New Jersey over MCC is proper under N.J. Ct. R. 4:4-4(a) and (b)(1) because it purposefully avails itself of the privilege of developing, marketing, and selling products and doing business in New Jersey to and through its agent and/ or alter ego Optonix, among other New Jersey entities; MCC has continuous and systematic contacts with New Jersey; and MCC can reasonably expect to be subject to jurisdiction in the courts of New Jersey.

53. Alternatively, personal jurisdiction in New Jersey over MCC is proper under Federal Rule of Civil Procedure 4(k)(2) even if MTPC is not subject to the jurisdiction of New Jersey because the claims asserted by Hikma and West-Ward arise under Federal law, MCC is not subject to the jurisdiction of any other state court, and exercising jurisdiction over MCC is consistent with U.S. law.

54. MCC and/or MTPC are necessary and indispensable parties to Plaintiffs' claims against Defendants.

55. On information and belief, MCC received Hikma's Paragraph IV Notice on or about June 3, 2011.

56. On information and belief, Pfizer and Encysive received Hikma's Paragraph IV Notice on or June 6, 2011.

57. On information and belief, MCC did not notify GSK of Hikma's Paragraph IV Notice within 45 days of receiving it.

58. On information and belief, Pfizer and Encysive did not notify GSK of Hikma's Paragraph IV Notice within 45 days of receiving it.

59. Neither Mitsubishi, Pfizer or Encysive sued Defendants for infringement of the '052 patent within 45 days of receiving Hikma's Paragraph IV Notice.

**COUNT I – DECLARATORY JUDGMENT OF NONINFRINGEMENT**

60. Defendants incorporate by reference, as if fully set forth herein, the preceding paragraphs of their Answer and Counterclaim.

61. Defendants have not infringed and are not infringing any claim of the '052 patent, literally or under the doctrine of equivalents either directly or indirectly and have not induced infringement or contributed to infringement by others.

**COUNT II – DECLARATORY JUDGMENT OF INVALIDITY**

62. Defendants incorporate by reference, as if fully set forth herein, the preceding paragraphs of their Answer and Counterclaim.

63. Each and every claim of the '052 patent is invalid for failure to comply with the requirements of 35 U.S.C. § 112.

**PRAYER FOR RELIEF**

WHEREFORE, Defendants pray that the Court enter a judgment that:

- A. Defendants have not infringed any valid claim of the '052 patent;
- B. Each and every claim of the '052 patent is invalid;
- C. Plaintiffs are not entitled to injunctive relief;
- D. Plaintiffs take nothing by this action;
- E. This be declared an exceptional case under 35 U.S.C. § 285, and that Defendants be awarded their costs, including reasonable attorneys' fees; and
- F. For such other relief as the Court deems just and proper.

**JURY DEMAND**

Defendants demand trial by jury of all issues triable to a jury.

Dated: May 21, 2012

Respectfully submitted,

**SAIBER LLC**

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**LOCAL CIVIL RULE 11.2 CERTIFICATION**

Under Local Civil Rule 11.2, the undersigned counsel for Defendants hereby certifies that this matter is not the subject of any other action asserted by Defendants in any court, or of any pending arbitration or administrative proceeding.

Dated: May 21, 2012

s/ Arnold B. Calmann

Arnold B. Calmann

**LOCAL CIVIL RULE 201.1 CERTIFICATION**

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Defendants hereby certifies that Defendants seek declaratory relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: May 21, 2012

s/ Arnold B. Calmann

Arnold B. Calmann